

IN THE CLAIMS

This listing of claims will replace all prior versions and listing of claims in the application. The following amendments are without prejudice and do not constitute an admission regarding the patentability of the amended subject matter and should not be so construed.

1. (Withdrawn) A method of improving the sexual performance in a male subject, comprising:

percutaneously delivering a pharmaceutically effective amount of a steroid in the testosterone synthetic pathway to the subject via a pharmaceutical composition comprising the steroid, at least one of a C1-C4 alcohol, and a penetration enhancer.

2. (Withdrawn) The method in claim 1 wherein the penetration enhancer comprises at least one of a C8-C22 fatty acid.

3. (Withdrawn) The method in claim 1 wherein the fatty acid comprises an alkyl chain length of at least 12 carbon atoms.

4. (Withdrawn) The method in claim 1 wherein the lower alcohol comprises at least one of ethanol, 2-propanol, n-propanol, and mixtures thereof.

5. (Withdrawn) The method in claim 1 wherein the steroid is testosterone and the enhancer is isopropyl myristate.

6. (Withdrawn) The method of claim 5 wherein the composition comprises about 1.0 g w/w of testosterone.

7. (Withdrawn) The method of claim 5 wherein the enhancer comprises about 0.5 g w/w of isopropyl myristate.

8. (Withdrawn) The method of claim 5 wherein the thickener is CARBOPOL.

9. (Withdrawn) The method of claim 1 where the steroid comprises about 0.5 g to about 5.0 g testosterone, the thickener comprises about 0.10 g to about 2 g of CARBOPOL, the enhancer comprises about 0.1 g to about 2 g of isopropyl myristate, the C1-C4 alcohol comprises about 40.0 g to about 90 g of ethanol.

10. (Withdrawn) The method in claim 1 wherein the men are hypogonadal.

11. (Withdrawn) The method in claim 10 wherein the men suffer from primary hypogonadism.

12. (Withdrawn) The method in claim 1 wherein the delivering occurs daily.

13. (Withdrawn) The method in claim 12 wherein the delivery comprises administering the composition to the right/left upper arms/shoulders and to the right/left sides of the abdomen once per day on alternate days.

14. (Withdrawn) The method in claim 1 wherein the pharmaceutically effective amount of steroid comprises 75 mg of testosterone per day.

15. (Withdrawn) The method in claim 14 wherein the men achieve hormonal steady state levels of testosterone.

16. (Withdrawn) The method in claim 1 wherein the improving sexual performance comprises treating impotence in the men.

17. (Withdrawn) A method of increasing the libido of men comprising:
delivering a pharmaceutically effective amount of a steroid in the testosterone synthetic pathway to the men percutaneously in a composition comprised of a C1-C4 alcohol, a penetration enhancer, a thickener, testosterone, and water.

18. (Withdrawn) The method in claim 17 wherein the penetration enhancer comprises at least one of a C8-C22 fatty acid.

19. (Withdrawn) The method in claim 17 wherein the fatty acid comprises an alkyl chain length of at least 12 carbon atoms.

20. (Withdrawn) The method in claim 17 wherein the lower alcohol comprises at least one of ethanol, 2-propanol, n-propanol, and mixtures thereof.

21. (Withdrawn) The method in claim 17 wherein the steroid is testosterone and the enhancer is isopropyl myristate.

22. (Withdrawn) The method of claim 21 wherein the composition comprises about 1.0 g w/w of testosterone.

23. (Withdrawn) The method of claim 21 wherein the enhancer comprises about 0.5 g w/w of isopropyl myristate.

24. (Withdrawn) The method of claim 21 wherein the thickener is CARBOPOL.

25. (Withdrawn) The method of claim 17 where the steroid comprises about 0.5 g to about 5.0 g testosterone, the thickener comprises about 0.10 g to about 2 g of CARBOPOL, the enhancer comprises about 0.1 g to about 2 g of isopropyl myristate, the C1-C4 alcohol comprises about 40.0 g to about 90 g of ethanol.

26. (Withdrawn) The method in claim 17 wherein the men are hypogonadal.

27. (Withdrawn) The method in claim 17 wherein the men suffer from primary hypogonadism.

28. (Withdrawn) The method in claim 17 wherein the delivering occurs daily.

29. (Withdrawn) The method in claim 28 wherein the delivery comprises administering the composition to the right/left upper arms/shoulders and to the right/left sides of the abdomen once per day on alternate days.

30. (Withdrawn) The method in claim 17 wherein the pharmaceutically effective amount of a steroid in the testosterone synthetic pathway comprises 75 mg of testosterone per day.

31. (Withdrawn) The method in claim 17 wherein the men achieve hormonal steady state levels of testosterone.

32. (Currently Amended) A method for improving the efficacy of a pharmaceutical other than testosterone, which pharmaceutical is useful for treating erectile dysfunction in a male subject, comprising:

percutaneously delivering a pharmaceutically effective amount of a steroid in the testosterone synthetic pathway to the subject in a composition comprising at least one of a C1-C4 alcohol, the steroid, a thickener, and a penetration enhancer; and

administering the pharmaceutical to the subject.

33. (Original) The method in claim 32 wherein the subject is eugonadal.

34. (Original) The method of claim 32 wherein the pharmaceutical is a phosphodiesterase type 5 inhibitor.

35. (Currently Amended) The method in claim 32 wherein the pharmaceutical is at least one of sildenafil citrate, pentoxifylline, yohimbine, apomorphine, alprostadil, papavaerine, phenotolamine, and combinations, salts, derivatives and enantiomers of thereof.

36. (Original) The method in claim 32 wherein the pharmaceuticals are selected from the group consisting of VIAGRA, UPRIMA, TRENTAL or ACTIBINE.

37. (Original) The method in claim 32 wherein the penetration enhancer comprises at least one of a C8-C22 fatty acid.

38. (Currently Amended) The method in claim 37 32 wherein the fatty acid comprises an alkyl chain length of at least 12 carbon atoms.

39. (Currently Amended) The method in claim 32 wherein the C1-C4 lower alcohol comprises at least one of ethanol, 2-propanol, n-propanol, and mixtures thereof.

40. (Original) The method in claim 32 wherein the steroid is testosterone and the enhancer is isopropyl myristate.

41. (Original) The method of claim 38 wherein the composition comprises about 1.0 g w/w of testosterone.

42. (Original) The method of claim 38 wherein the enhancer comprises about 0.5 g w/w of isopropyl myristate.

43. (Currently Amended) The method of claim 32 38 wherein the thickener is CARBOPOL.

44. (Original) The method of claim 32 wherein the steroid comprises about 0.5 g to about 5.0 g testosterone, the thickener comprises about 0.10 g to about 2 g of CARBOPOL, the enhancer comprises about 0.1 g to about 2 g of isopropyl myristate, the C1-C4 alcohol comprises about 40.0 g to about 90 g of ethanol.

45. (Currently Amended) The method in claim 32 wherein the male subject is men are hypogonadal.

46. (Currently Amended) The method in claim 32 wherein the male subject men suffers from primary hypogonadism.

47. (Original) The method in claim 32 wherein the delivering occurs daily.

48. (Currently Amended) The method in claim 32 wherein the delivery comprises administering the composition to the right/left upper arms/shoulders or and to the right/left sides of the abdomen once per day on alternate days.

49. (Original) The method in claim 32 wherein the pharmaceutically effective amount of steroid comprises 75 mg of testosterone per day.

50. (Currently Amended) The method in claim 32 wherein the ~~men~~ male subject achieves hormonal steady state levels of testosterone.

51. (Withdrawn) A kit comprised of a pharmaceutical useful for treating erectile dysfunction in a man and a transdermal testosterone gel.

52. (Withdrawn) The kit of claim 51 wherein the pharmaceutical is a phosphodiesterase type 5 inhibitor.

53. (New) A method for improving the efficacy of a pharmaceutical useful for treating erectile dysfunction in a eugonadal male subject, comprising:

percutaneously delivering a pharmaceutically effective amount of testosterone to the subject in a composition comprising at least one of a C1-C4 alcohol, a thickener, and a penetration enhancer; and

administering the pharmaceutical to the subject.

54. (New) The method of claim 53 wherein the pharmaceutical is a phosphodiesterase type 5 inhibitor.

55. (New) The method in claim 53 wherein the pharmaceuticals are selected from the group consisting of VIAGRA, UPRIMA, TRENTAL or ACTIBINE.

56. (New) The method in claim 53 wherein the penetration enhancer comprises at least one of a C8-C22 fatty acid.

57. (New) The method in claim 56 wherein the fatty acid comprises an alkyl chain length of at least 12 carbon atoms.

58. (New) The method in claim 53 wherein the C1-C4 alcohol comprises at least one of ethanol, 2-propanol, n-propanol, and mixtures thereof.

59. (New) The method in claim 53 wherein the enhancer is isopropyl myristate.

60. (New) The method of claim 53 wherein the thickener is CARBOPOL.

61. (New) The method of claim 53 wherein the composition comprises about 0.5 g to about 5.0 g testosterone, the thickener comprises about 0.10 g to about 2 g of CARBOPOL, the enhancer comprises about 0.1 g to about 2 g of isopropyl myristate, the C1-C4 alcohol comprises about 40.0 g to about 90 g of ethanol.

62. (New) The method of claim 53 wherein the pharmaceutically effective amount of testosterone is 75 mg per day.

63. (New) A method for improving the efficacy of a phosphodiesterase type 5 inhibitor useful for treating erectile dysfunction in a male subject, comprising:

percutaneously delivering a pharmaceutically effective amount of a steroid in the testosterone synthetic pathway to the subject in a composition comprising at least one of a C1-C4 alcohol, the steroid, a thickener, and a penetration enhancer; and

administering the inhibitor to the subject.

64. (New) The method in claim 63 wherein the phosphodiesterase type 5 inhibitor is selected from the group consisting of VIAGRA, UPRIMA, TRENTAL or ACTIBINE.

65. (New) The method in claim 63 wherein the penetration enhancer comprises at least one of a C8-C22 fatty acid.

66. (New) The method in claim 65 wherein the fatty acid comprises an alkyl chain length of at least 12 carbon atoms.

67. (New) The method in claim 63 wherein the C1-C4 alcohol comprises at least one of ethanol, 2-propanol, n-propanol, and mixtures thereof.

68. (New) The method in claim 63 wherein the enhancer is isopropyl myristate.

69. (New) The method of claim 63 wherein the thickener is CARBOPOL.

70. (New) The method of claim 63 where the steroid comprises about 0.5 g to about 5.0 g testosterone, the thickener comprises about 0.10 g to about 2 g of CARBOPOL, the enhancer comprises about 0.1 g to about 2 g of isopropyl myristate, the C1-C4 alcohol comprises about 40.0 g to about 90 g of ethanol.

71. (New) A method for improving the efficacy of a pharmaceutical useful for treating erectile dysfunction in a male subject, comprising:

percutaneously delivering a pharmaceutically effective amount of a steroid in the testosterone synthetic pathway to the subject in a composition comprising at least one of a C1-C4 alcohol, the steroid, a thickener, and a penetration enhancer; and

orally administering the pharmaceutical to the subject.